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DEC 19 2013

510(k) Summary

As required by 21 CFR 807.92, this "510(k) Summary" provides a basis for the substantial equivalence determination of the device listed below.

General Information

Date Prepared:	April 5, 2013
Submitter Name:	Xeridiem Medical Devices [formerly Manufacturing and Research, Inc.]
Submitter Address:	4700 S. Overland Dr. Tucson, Az 85714
Contact Person:	Michelle Lott, RAC
Phone Number:	(520) 882-7794
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Device Information

Trade Name:	Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube
Common Name:	Gastrostomy Tube
Classification Name:	Tubes, gastrointestinal (and accessories) [21 CFR 876.5980, Product Code KNT]
Classification Panel:	Gastroenterology/Urology

Predicate Device Information

Trade Name:	EndoVive™ Standard Replacement Gastrostomy Tube (K083684)
Common Name:	Gastrostomy Tube
Classification Name:	Tubes, gastrointestinal (and accessories) [21 CFR 876.5980, Product Code KNT]
Classification Panel:	Gastroenterology/Urology

Device Description

The Entuit ™ Thrive Balloon Retention Gastrostomy Feeding Tube is constructed primarily of silicone. The device consists of a tri-port funnel which is overmolded onto a previously extruded bi-lumen shaft. A retention bolster is molded separately and placed over the shaft. At the proximal end, a silicone balloon is bonded to the shaft using silicone RTV. The tip of the shaft is filled with radiopaque barium RTV. In use, the balloon end of the catheter is inserted through a gastrointestinal stoma tract and into the stomach lumen. The balloon is then inflated to the rated volume using sterile or distilled water and the bolster adjusted down to the skin to secure the device in place.

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Intended Use/Indications for Use

The Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube is intended to provide gastric access for enteral feeding, medication administration and decompression through an established gastrointestinal stoma tract.

The Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube is indicated for use in percutaneous placement of an enteral feeding tube in adult and pediatric patients that require enteral feeding, medication administration or decompression through an established gastrointestinal stoma tract.

Technological Characteristics

The table below provides a general summary of the technological characteristics of the Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube compared to the predicate device.

Technological Characteristics		
	Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube (Submitted device)	**EndoVive™ Standard Replacement Gastrostomy Tube (Predicate Device) K083684**
Product Range (FR size)	12 - 24 FR	12 - 28 FR
Product Range (Length)	10 cm	10 cm
Product Range (Balloon Size)	5 cc for 12 - 18 FR devices 20cc for 20 – 24 FR devices	4 cc for 12 FR device 6 cc for 14 – 28 FR devices
Funnel	Similar – Silicone with 3 ports: one for feeding, one for medication and the other for balloon inflation. Adapter added to medication port plug.	Silicone with 3 ports: one for feeding, one for medication and the other for balloon inflation
Bolster	Silicone 40 durometer in straight configuration – different bolster profile	Silicone 60 durometer in two configurations: one straight and one right angle
Inflation valve	Similar - Thermoplastic housing with silicone valve (low profile valve)	Thermoplastic housing with silicone valve
Balloon	Same materials as K083684, different balloon profile	Silicone pancake shaped balloon
Shaft	Same as K083684	Silicone 65 durometer
Barium stripe	Barium sulfate without colorant	Barium sulfate with blue colorant
Kit Contents	No accessory devices included with device	Inflation syringe, gauze and lubricating jelly
Packaging System/Materials	Same as K083684	Tyvek Pouch, Polybag, IFU, Corrugate Case & Shipper

Performance Characteristics

The table below provides a general summary of the performance testing that was conducted for the Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube.

Test Method Conclusion

Test	Method	Conclusion
-Flow rate -Balloon Burst Volume -Balloon Volume Maintenance -Balloon Concentricity -Balloon Over Shaft Size -Balloon Integrity -Balloon Integrity in simulated gastric fluid	All in accordance to ASTM F2528-06 (*Procedures A through G*)	Candidate device met all performance requirements. Where acceptance criteria were not defined in the standard, the candidate device performed equivalent to or better than the predicate device.

In all instances the Entuit ™ Thrive Balloon Retention Gastrostomy Feeding Tube performed as intended.

Substantial Equivalence – Comparison to Predicate Device

Among the information and summary tables presented in the 510(k) submission to support substantial equivalence of the Entuit ™ Thrive Balloon Retention Gastrostomy Feeding Tube to the legally marketed predicate device are: 1.) device description, 2.) indications for use, 3.) device comparison tables, 4.) material information, 5.) bench test results, and 6.) labeling. In particular, bench testing demonstrates that there was no difference in the performance, safety, or effectiveness between the Entuit ™ Thrive Balloon Retention Gastrostomy Feeding Tube and the EndoVive™ Standard Replacement Gastrostomy Tube.

The Entuit ™ Thrive Balloon Retention Gastrostomy Feeding Tube is substantially equivalent to the EndoVive™ Standard Replacement Gastrostomy Tube (K083684).

The subject device and predicate device have the same intended use and similar indications, technological characteristics and principles of operation. The minor differences in technological characteristics have been identified and do not present any new issues of safety or effectiveness. Thus, the Entuit ™ Thrive Balloon Retention Gastrostomy Feeding Tube is substantially equivalent to the EndoVive™ Standard Replacement Gastrostomy Tube (K083684).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

Xeridiem Medical Devices
Michelle Lott
RA/QA Director, RAC
4700 S. Overland Drive
Tucson, AZ 85714

Re: K130611
Trade/Device Name: Entuit™ Thrive Balloon Retention Gastronomy Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: November 27, 2013
Received: November 29, 2013

Dear Michelle Lott,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Glenn D Bell -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K130611

Device Name: **Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube**

Indications For Use:

The Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube is intended to provide gastric access for enteral feeding, medication administration and decompression through an established gastrointestinal stoma tract.

The Entuit™ Thrive Balloon Retention Gastrostomy Feeding Tube is indicated for use in percutaneous placement of an enteral feeding tube in adult and pediatric patients that require enteral feeding, medication administration or decompression through an established gastrointestinal stoma tract.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Glenn B. Bell -S